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09/554,387	06/29/2000	BERND FABRY	H-3185-PCT/U	2050

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EXAMINER
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JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

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24

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/554,387  
Filing Date: June 29, 2000  
Appellant(s): FABRY, BERND

Paper No. 24

*mailed out  
date 6.18.00*

Aaron R. Ettelman  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed March 31, 2003.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

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**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is substantially correct. However, the examiner disagrees Appellant's statement "Appellant's invention is a significant and unexpected improvement over the prior art" (see the last sentence of the first paragraph of Appellant's *Summary of Invention*, it is noted that this statement is not referred to the specification by page and line number) and Appellant's explanation of the data in Examples of the specification (see the last paragraph of Appellant's *Summary of Invention*, it is noted that this statement is not referred to the specification by page and line number).

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Claims 11-30 stand or fall together.

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**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

US 3,865,939	Jandacek	02-1975
EP 0 594 612 B1	Miettinen et al.	08-1997
5,277,910	Hidvegi	01-1994

Hasegawa et al. "Hypocholesteremic effect of linoleic acid and phytosterol", Joshi Eiyo Daigaku Kiyo, (1983), Vol. 14, page 165-172 (Chemical Abstract No. 100:208354).

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939) and Hasegawa et al. in view of Miettinen et al. (EP 0594612B1), and Hidvegi (5,277,910). This rejection is set forth in the prior Office Action mailed April 22, 2002 in Paper No. 16.

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**(11) Response to Argument**

**Claim Rejections - 35 USC § 103 Maintained**

Claims 11-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939) and Hasegawa et al. in view of Miettinen et al. (EP 0594612B1), and Hidvegi (5,277,910) for reasons of record stated in the prior Office Action mailed April 22, 2002 in Paper No. 16.

The broadest claim in the instant application is drawn to a method of reducing serum cholesterol content in a mammal, comprising administering to the mammal an effective amount of a combination of (a) phytosterols or phytosterol esters, and (b) conjugated fatty acids having from about 6-24 carbons or glycerides of conjugated fatty acids having from about 6-24 carbons.

It is the examiner's position that the present invention is obvious in view of the prior art of record, as discussed below.

Appellant's primary argument is that that the Examiner has failed to established a prima facie case upon the cited references since the Examiner fail to show three criteria for a prima facie case because "none of the four references contains a teaching or suggestions which would motivate one of ordinary skill in the art to modify the teachings of the references to use a conjugated fatty acid" and "one of ordinary skill in the art would NOT have a reasonable expectation of success based on the cited references" (see Appellant's Brief on Appeal at page 11).

As indicated in the prior Office Action (April 22, 2002 and August 29, 2001), Jandacek discloses that phytosterols (synonymously phytosterols) have significant

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hypocholesterolemic activities. Jandacek also discloses that phytosterols such as  $\beta$ -sitosterol (synonymously  $\beta$ -sitostenol) along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms or glycerides of such fatty acids within the instant claimed compounds in an effective amount or combined with foodstuffs are useful for reducing serum cholesterol content in a mammal. See col.1 lines 5-14, col.2 lines 1-5, col.3 lines 27-28, col.4 lines 41-44, Table I, col.5 lines 17-31, Example I and claims 1, 3 and 6. Jandacek teaches broadly the usefulness of phytosterols such as  $\beta$ -sitosterol (synonymously  $\beta$ -sitostenol) along with saturated and unsaturated fatty acids having from 6 to 18 carbon atoms in the instant claimed method. Jandacek further teaches that the concentration level of phytosterols and saturated and unsaturated fatty acids having 6 to 18 carbon atoms in the hypocholesterolemic composition should be about 2.0 to about 6.0 wt.% and 0.5 to 15 wt.%, respectively, within the instant claims. See claim 1 and col.5 lines 17-23.

Hasegawa et al. teaches that the particular fatty acid, linoleic acid, and/or phytosterol including sitosterol (sitostenol) are useful for lowering the serum cholesterol in human mammals. Hasegawa et al. also teaches the vegetable oils have hypocholesteremic effects since they are high in linoleic acid and sitosterol. See the abstract. One of ordinary skill in the art would clearly recognize that the known structure of linoleic acid is substantially similar to the structure of conjugated linoleic acid because they are structural isomers which have two double bonds but merely differ in one position of one double bond (see the structure of linoleic acid provided by The Merck

Index at page 5526, attached).

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Miettinen et al. teaches that  $\beta$ -sitosterol ( $\beta$ -sitostenol) and  $\beta$ -sitostanol and their fatty acid esters are known to be useful to lower serum cholesterol levels. See page 2 lines 5-7 and claim 1. Miettinen et al. further teaches that usable fatty acids therein contain approx. 2-22 carbon atoms such as fatty acids in vegetable oil, i.e., rapeseed oil within the instant claims. See page 3 lines 44-45 and Example 1 on page 4. It is well known that many vegetable oils including rapeseed oil contain unsaturated fatty acids having one or more double bonds such as linoleic acid (see attached The Merck Index at page 5526). Miettinen et al. teaches broadly the usefulness of fatty acid esters of  $\beta$ -sitosterol ( $\beta$ -sitostenol) and  $\beta$ -sitostanol containing approx. 2-22 carbon atoms including unsaturated fatty acid esters in the instant claimed method. Miettinen et al. further discloses that  $\beta$ -sitostenol fatty acid ester mixture dissolved in rapeseed oil (containing unsaturated fatty acids having one or more double bonds such as linoleic acid, as active agents) decreased total cholesterol by 9.5% more and LDL cholesterol by 11.6% more than did rapeseed oil alone (see particularly page 4 lines 22-24). Thus, the teachings of Miettinen et al. are seen to provide the motivation for the combination of phytosterol esters and fatty acids broadly including linoleic acid, employed in the instant claimed method.

Hidvegi discloses a pharmaceutical composition for lowering the blood-lipid level containing sitosterol and fatty acids such as linoleic acid formulated into gelatin capsules. See col.1 lines 59-65, col.2 line 37, col.3 line 38 and col.8 lines 18-28.

The cited prior art herein does not expressly disclose the employment of a phytosterol or phytosterol esters in combination with particular unsaturated fatty acids

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such as conjugated fatty acids, e.g., conjugated linoleic acid, in methods of reducing serum cholesterol content.

As discussed in the prior Office Actions, one having ordinary skill in the art at the time the invention was made would have been motivated to employ a phytosterol such as  $\beta$ -sitosterol, combined with a particular unsaturated fatty acid having from 6 to 18 carbon atoms such as a conjugated fatty acid having from 6 to 18 carbon atoms, e.g., conjugated linoleic acid, or employ a particular carboxylic acid ester of a phytosterol (phytosterol) such as a  $\beta$ -sitosterol ( $\beta$ -sitosterol) esters having from 2 to 22 carbon atoms and up to about 3 double bonds, in combination with a particular unsaturated fatty acid having from 6 to 18 carbon atoms such as a conjugated fatty acid having from 6 to 18 carbon atoms, for use in methods of reducing serum cholesterol content because a phytosterol or phytosterol esters having an unsaturated fatty acid from 6 to 18 carbon atoms, e.g., linoleic acid (and also including conjugated linoleic acid), alone or in combination with fatty acids broadly such as linoleic acid (and also including conjugated linoleic acid) are known to be useful in the instant claimed method for reducing serum cholesterol content in a mammal according to the cited prior art herein. The motivation for the combination of phytosterol esters and fatty acids broadly including linoleic acid and also including conjugated linoleic acid, employed in the instant claimed method, has been provided by Miettinen et al. Importantly, the particular fatty acid, linoleic acid, alone or in combination with a phytosterol or phytosterol esters is known to be useful in the instantly claimed, according to the prior art of record.



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Moreover, one of ordinary skill in the art would have reasonably expected that combining a fatty acid broadly and of a phytostenol or of phytostenol esters of a fatty acid herein known useful for the same purpose in a composition to be administered would improve the therapeutic effect for reducing serum cholesterol content in a mammal. At least some additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) which renders the claims prima facie obvious.

Appellant argues that the Examiner has failed to established a prima facie case upon the cited references since the Examiner fail to show three criteria for a prima facie case (see Appellant's Brief on Appeal at page 7) because "none of the four references contains a teaching or suggestions which would motivate one of ordinary skill in the art to modify the teachings of the references to use a conjugated fatty acid" and "one of ordinary skill in the art would NOT have a reasonable expectation of success based on the cited references" (see Appellant's Brief on Appeal at page 11). Appellant's arguments have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

According to MPEP 2144.08, if such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *Deuel*, 51 F.3d at 1558, 34 USPQ2d at 1214. The utility of such properties will normally provide some motivation to make the

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claimed species or subgenus. See Dillon, 919 F.2d at 697, 16 USPQ2d at 1904-05 (and cases cited therein).

In the instant case, as discussed above, the structure of linoleic acid is known to be substantially similar to the structure of the claimed conjugated linoleic acid because they are structural isomers having two double bonds but merely differing in the position of one of double bonds. One of ordinary skill in the art would have a reasonable expectation of success by employing the instant conjugated linoleic acid in the claimed method of reducing serum cholesterol content since structurally similar species usually have similar properties. Linoleic acid or fatty acids broadly (which may includes conjugated linoleic acid) are known to have hypocholesterolemic properties or activities. Thus, conjugated linoleic acid, structurally substantially similar to linoleic acid would also be expected to have hypocholesterolemic properties or activities.

MPEP 2144.08 continues: if the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species, In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have very close' structural similarities and similar utilities, without more a prima facie case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious.

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Dillon, 919 F.2d at 697-98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). In the instant case, the motivation for employing conjugated linoleic acid having similar properties and utilities as linoleic acid in the claimed method herein is sufficiently seen as discussed above.

Additionally, since all active composition components herein are known to useful to reduce serum cholesterol content in a mammal, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected based on the well settled principle set forth *In re Kerkhoven* regarding combination inventions. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145. Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art of record.

Therefore, the three criteria for a prima facie case in Appellant's arguments (see page 7-11) are met for the instant case based on above discussion.

Appellant's arguments regarding the claimed significantly improved results (see Appellant's Brief on Appeal at page 12-15) in Appellant's data of Examples and Table 1 in the specification at pages 8-9 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art

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but are not deemed persuasive for the reasons below. It is noted that lauric acid in lauric acid  $\beta$ -sitostanol ester or lauric acid  $\beta$ -sitostenol ester employed in the testing herein is not even an unsaturated carboxylic acid (having no double bond), which is not the instant preferred carboxylic acid having up to 3 double bonds (see claims 13-14 herein).

The results on the tests of the employment of  $\beta$ -sitostenol,  $\beta$ -sitostanol, or their esters, combined with conjugated linoleic acid in the composition administered to rats in Table 1 in the specification, showing some additive effects on reducing the cholesterol content in rats, would be expected based on the teachings of Miettinen et al. that the combination of  $\beta$ -sitostenol fatty acid esters and rapeseed oil (containing fatty acids such as linoleic acid as active agents) exhibits additive effects by decreasing total cholesterol more and LDL cholesterol more than fatty acids alone, and the disclosure of Hasegawa et al. that linoleic acid and phytosterol are known to have hypocholestermic effect in human mammals, and that conjugated linoleic acid, structurally similar to linoleic acid, usually have similar properties and similar utilities as linoleic acid, as discussed above. Moreover, at least additive therapeutic effects would have been reasonably expected based on the well settled principle set forth *In re Kerkhoven* regarding combination inventions. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c).

Further, the specification provides no side-by-side comparison between the employment of unconjugated fatty acids and conjugated fatty acids with  $\beta$ -sitostenol,  $\beta$ -sitostanol, or its esters in the claimed method herein. Thus, the results

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herein are insufficient to clearly demonstrate any possible unexpected supra additive effects for the combination of conjugated fatty acids with  $\beta$ -sitostenol,  $\beta$ -sitostanol, or its esters over the cited prior art.

Furthermore, the tests herein merely employ the combination of two particular phytostenols,  $\beta$ -sitostenol or  $\beta$ -sitostanol in combination with the particular conjugated fatty acid, conjugated linoleic acid. Thus, the evidence in the testing is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of phytostenol compounds and conjugated fatty acids herein. See MPEP § 716.02(d).


Therefore, no clear and convincing evidence of nonobviousness or unexpected results for the combination of a phytostenol or its ester and a conjugated fatty acid in the claimed method presented in specification herein is seen to support the nonobviousness of the instant claimed invention over the prior art of record.

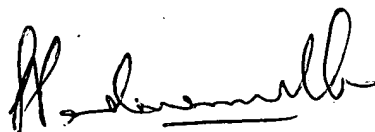
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

  
S. A. Jiang, Ph.D.  
June 16, 2003

Conferees

  
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